

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

-----X
GLAXO GROUP LIMITED

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC. and
TEVA PHARMACEUTICAL INDUSTRIES
LIMITED

Defendants.
-----X

Civil Action No. 04-171-KAJ

REDACTED VERSION

**PLAINTIFF GLAXO'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR
SUMMARY JUDGMENT DISMISSING DEFENDANTS' AFFIRMATIVE DEFENSES
AND CORRESPONDING COUNTERCLAIM ALLEGING INEQUITABLE CONDUCT
DURING THE PROSECUTION OF U.S. PATENT NO. 5,068,249**

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I. INTRODUCTION

Pursuant to Paragraph 10 of the Scheduling Order, as amended, Plaintiff Glaxo Group Limited ("Glaxo") submits this reply brief in support of its Motion For Summary Judgment Dismissing Defendants' Affirmative Defenses And Corresponding Counterclaim Alleging Inequitable Conduct During The Prosecution Of U.S. Patent No. 5,068,249 submitted on June 30, 2006 (D.I. 96) and in response to Teva's Brief In Opposition To Glaxo's Motion submitted on July 28, 2006 (D.I. 125) ("Answ. Br."). In support of this reply brief, Glaxo relies on the Declarations of Oren D. Langer¹ and Bradley D. Anderson, Ph.D.² Glaxo respectfully submits that it is entitled to entry of summary judgment in its favor dismissing Teva Pharmaceuticals USA, Inc.'s ("Teva USA") Third Affirmative Defense and corresponding counterclaim (Count III) and Teva Pharmaceutical Industries Limited's ("Teva Israel") Third and Fourth Affirmative Defenses alleging inequitable conduct.³

II. SUMMARY OF ARGUMENT

Defendant states in its answering brief that it has a right to litigate the issue of inequitable conduct in this case. (Answ. Br. at 11). Defendant, however, has failed to identify any new

¹ "Langer Decl." refers to the "Declaration of Oren D. Langer, Esq., in Support of Plaintiff Glaxo Group Limited's Opening Claim Construction Brief and Summary Judgment Motions on U.S. Patent No. 5,068,249" submitted on June 30, 2006. (D.I. 99 (Exhibits 1-25) and D.I. 100 (Exhibits 26-48)). "Langer Suppl. Decl." refers to the "Supplemental Declaration of Oren D. Langer, Esq., in Support of Plaintiff Glaxo Group Limited's Answering Brief to Teva's Motion for Summary Judgment of Non-Infringement" submitted on July 28, 2006. (D.I. 124). "Langer 2d Suppl. Decl." refers to the "Second Supplemental Declaration of Oren D. Langer, Esq., in Support of Plaintiff Glaxo Group Limited's Reply Memorandum in Support of Its Motion for Summary Judgment of Infringement" submitted herewith.

² "Anderson Decl." refers to "Declaration of Bradley D. Anderson, Ph.D., in Support of Plaintiff Glaxo Group Limited's Opening Claim Construction Brief on U.S. Patent No. 5,068,249" submitted on June 30, 2006. (D.I. 98).

³ Teva USA and Teva Israel are collectively referred to as "Teva" or "defendant."

evidence or arguments that would satisfy its burden of identifying clear and convincing evidence in support of its defense. Defendant chose not to take any fact depositions. Defendant chose not to depose Dr. David Long or Dr. John Hempenstall. Defendant chose to rely on the identical evidence and arguments presented to Judge Davis in *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265, 310-13 (D. Md. 1998) (the "*Pharmadyne* case"), to support its inequitable conduct defense. Judge Davis thoroughly considered the evidence. *Id.* He observed the demeanor of witnesses Dr. Long and Dr. Hempenstall while testifying under oath at trial. *Id.* He questioned both witnesses, particularly Dr. Hempenstall, and he considered the Tagamet® Physicians' Desk Reference ("PDR") entry and the Fiona Bird memo.⁴ *Id.* Judge Davis ultimately rejected Pharmadyne's inequitable conduct defense. *Id.* Under these circumstances, defendant's decision to rely exclusively on the identical evidence and arguments as in the *Pharmadyne* case may give rise to collateral estoppel,⁵ but even if not, defendant has surely failed to identify any new evidence or arguments that would satisfy its burden of identifying clear and convincing evidence in support of its defense. Glaxo submits that the record compels dismissal of defendant's inequitable conduct defense.

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⁵ See *Burlington Northern Railroad Co. v. Hyundai Merchant Marine Co., Ltd.*, 63 F.3d 1227, 1231-32 (3d Cir. 1995); see also *Tauro v. A Yet Unnamed Domestic*, No. 05-5483, 2006 WL 2374280 (3d Cir. Aug. 16, 2006) (unpub.) (affirming dismissal of claim *sua sponte* on the basis of collateral estoppel) (Exhibit A); *Turner v. Correctional Med. Servs.*, No. 06-095, 2006 U.S. Dist. LEXIS 25910, at *6 (D. Del. May 1, 2006) (noting court's power to dismiss claims *sua sponte* that are barred by collateral estoppel) (Exhibit B). Defendant fails to offer any explanation for why it took no fact depositions or why its decision to rely on the identical evidence and arguments as in the *Pharmadyne* case does not satisfy considerations of due process for purposes of collateral estoppel or issue preclusion. See *Blonder-Tongue Labs., Inc. v. Univ. of Illinois Foundation*, 402 U.S. 313, 329 (1971).

There are no disputed issues of material fact here. The material facts, as found by Judge Davis in the *Pharmadyne* opinion, are based on the identical testimonial and documentary evidence raised by defendant in this case. The parties have stipulated to the admissibility of the deposition and trial testimony of Drs. Long and Hempenstall, the Tagamet® PDR entry, and the Fiona Bird memo, all of which were admitted into evidence in the *Pharmadyne* case.⁶ Defendant repeatedly cites the *Pharmadyne* case to support its position but does not offer any new evidence or legal analysis that could possibly alter Judge Davis' conclusion of no inequitable conduct. It would be a waste of judicial resources and the resources of Dr. Long, Dr. Hempenstall, defendant and Glaxo to retry this issue when defendant has not even bothered to look for any new evidence or to present any new arguments.

Defendant's answering brief is premised on its belief that it should have a chance to "mak[e] its own arguments and present[] its own evidence on the materiality and intent of Glaxo's omissions to the Patent Office, *even if the arguments and evidence are the same.*" (Answ. Br. at 11) (emphasis added). When a motion for summary judgment is made, the adverse party has the burden of coming forward with specific material facts showing that there is a genuine issue for trial. See Fed. R. Civ. P. 56(e). Defendant's arguments and evidence are, in fact, identical to those in the *Pharmadyne* case. Regurgitating the identical evidence that has already been thoroughly considered and rejected by a federal district court judge in a thoughtful, comprehensive opinion is insufficient to show that there is a genuine issue for trial and to avoid summary judgment.

⁶ The Tagamet® PDR and the Fiona Bird memo were admitted into evidence in the *Pharmadyne* case as DX 105 and 7, respectively.

Glaxo submits that the record supports a dismissal of defendant's inequitable conduct defense. Glaxo respectfully requests that the Court enter summary judgment in favor of Glaxo on the issue of inequitable conduct and dismiss Teva USA's Third Affirmative Defense and corresponding counterclaim (Count III) and Teva Israel's Third and Fourth Affirmative Defenses pursuant to Fed. R. Civ. P. 56.

III. ARGUMENT

A. Defendant Has Failed To Satisfy Its Burden Of Setting Forth Specific Material Facts Demonstrating A Genuine Issue For Trial

To defeat Glaxo's motion for summary judgment, defendant must do "more than simply show that there is some metaphysical doubt as to the material facts," more than merely present some evidence on an issue it asserts is disputed or just rest on mere allegations. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986); *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 248 (1986); *Biotec Biologische Naturverpackungen GmbH & Co. KG v. Blocorp, Inc.*, 249 F.3d 1341, 1353 (Fed. Cir. 2001) ("It is well established that conclusory statements of counsel or a witness . . . do not raise a genuine issue of fact."); *Shamrock Techs., Inc. v. Medical Sterilization, Inc.*, 903 F.2d 789, 792 (Fed. Cir. 1990). "A party asserting that a patent is unenforceable due to inequitable conduct must prove materiality and intent by clear and convincing evidence. Once threshold findings of materiality and intent are established, the trial court must weight them to determine whether the equities warrant a conclusion that inequitable conduct occurred. . . . [T]he less material the information, the greater the proof must be." *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, 438 F.3d 1123, 1128-29 (Fed. Cir. 2006) (citations omitted); see also *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001). The clear and convincing evidence standard can only be met where the fact finder has "an abiding conviction that the truth of [the] factual contentions are 'highly

probable.’ ” *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 228 F. Supp. 2d 480, 496 (D. Del. 2002) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

In considering proof of intent, the Court must neither presume nor infer it from evidence of materiality. *See Purdue Pharma*, 438 F.3d at 1134 (“Intent to deceive, however, cannot be ‘inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.’ ”) (quoting *Herbert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996)). A threshold showing of intent is required even if there is a high degree of materiality. *See Upjohn Co. v. Mova Pharm. Corp.*, 225 F.3d 1306, 1312 (Fed. Cir. 2000) (“‘[M]ateriality does not presume intent, which is a *separate and essential* component of inequitable conduct.’ ”) (emphasis added) (quoting *Marville Sales Corp. v. Paramount Systems, Inc.*, 917 F.2d 544, 552 (Fed. Cir. 1990)); *see also Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1442 (Fed. Cir. 1991) (“[T]he materiality of an undisclosed reference does not presume an intent to deceive.”). Defendant has failed to set forth specific material facts demonstrating a genuine issue for trial on the issues of materiality and intent. *See Fed. R. Civ. P. 56(e); Biotec*, 249 F.3d at 1353-54 (concluding that the nonmovant provided mere conclusory statements and failed to raise a genuine issue of material fact).

1. There Are No Triable Issues Of Material Fact To Support Defendant's Allegations Of Materiality And Intent Concerning The Tagamet® PDR Entry

Defendant cannot satisfy its burden of proof or point to any specific material facts to support its claim that Dr. Long committed inequitable conduct by not disclosing the Tagamet® PDR entry to the United States Patent and Trademark Office (“PTO”). The undisputed evidence demonstrates that the Tagamet® PDR entry is not material to the claims of the ‘249 patent and is, at most, cumulative of the prior art references already reviewed and considered by the PTO

Examiner. *See Pharmadyne*, 32 F. Supp. 2d at 310-311. Defendant does not, and cannot, dispute the following material facts:

- The Tagamet® solution contains cimetidine, not ranitidine, as the active ingredient.

See id. at 301, 310. (*See also* Wray Tr.⁷ 501-02, 4812-13, Langer Decl., Ex. 15;

Wood Tr.⁸ 73-75, Langer Decl., Ex. 2;

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- The Tagamet® PDR entry does not disclose or suggest that ethanol could be used to enhance the stability of ranitidine in an aqueous formulation for oral administration.

See id. at 301.

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- There are clear chemical differences between cimetidine and ranitidine, including the following: (1) cimetidine and ranitidine are not the same type of compound, *see id.* at 301, 310 (*see also* Wray Tr. 501-02, 4812-13, Langer Decl., Ex. 15; Wood Tr. 73-75, Langer Decl., Ex. 2; **REDACTED** (2) cimetidine is a guanadine, and ranitidine is an enamine, *see id.* (*see also* Wray Tr. 4813, Langer Decl., Ex. 15);

⁷ “Wray Tr.” refers to the trial testimony of Dr. Paul Wray in the *Pharmadyne* case. Although defendant has not stipulated to the admissibility of Dr. Wray’s testimony in this case, defendant does not dispute its accuracy and its probity as to the differences between cimetidine and ranitidine. (Answ. Br. at 12). These differences are undisputed. *See Pharmadyne*, 32 F. Supp. 2d at 301, 310-11. Dr. Wood testified to the chemical and clinical differences between cimetidine and ranitidine. (Wood Tr. 73-75, Langer Decl., Ex. 2).

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⁸ “Wood Tr.” refers to the trial testimony of Dr. John Wood in the *Pharmadyne* case.

⁹ “Anderson Rebuttal Rpt.” refers to “Bradley D. Anderson, Ph.D., Fed. R. Civ. P. 26(a)(2) Rebuttal Expert Witness Report” attached as Exhibit B to the Anderson Declaration.

(3) cimetidine and ranitidine have different ring structures in addition to differences in their side chains, *see id.* (*see also* Wray Tr. 4813, Langer Decl., Ex. 15); and

(4) cimetidine causes side-effects in patients that are not present in patients taking a ranitidine product, *see Pharmadyne*, 32 F. Supp. 2d at 301 (*see also* Wood Tr. 73, Langer Decl., Ex. 2).

- During the prosecution of the applications that led to the '249 patent, the Examiner reviewed two Chemical Abstracts which specifically referenced ranitidine. The Examiner understood these references to teach "the cojoined use of use of [*sic*] ranitidine and an alcohol (ethanol)" and rejected all of the claims numerous times on this ground. *See id.* at 311. (*See also* '249 File History at G000264-65, G000272, G000132, G000161, G000171, Langer Decl., Ex. 10).
- During the prosecution of the applications that led to the '249 patent, applicant acknowledged that ethanol previously had been used in pharmaceutical compositions as a solvent or preservative against bacterial contamination but not as a ranitidine stabilizer. *See id.* (*See also* '249 File History at G000205, Langer Decl. Ex. 10).
- Similarly, defendant admitted in its Amended Responses to Glaxo's interrogatories that the Tagamet® PDR entry merely "teaches ethanol as a preservative in pharmaceutical syrups for cimetidine, a H₂ receptor antagonist drug that is similar to ranitidine." (Teva USA's Answer to Interrogatory No. 7 at p. 13, Langer 2d Suppl. Decl., Ex. 1).
- Dr. Long testified during the *Pharmadyne* case that he used the Tagamet® solution as a gauge for knowing whether ethanol could be used in a formulation that would be

used to treat ulcer-type ailments, but did not know why the ethanol was in the

Tagamet® solution:

To give us *comfort in that could we use ethanol in a syrup for the treatment of ulcers*, we were well aware of in the public domain that alcohol was a constituent of Tagamet liquid, so we knew, we knew that another manufacturer was including ethanol. *We had no idea why, I still don't know why*, but there was precedent.

(Long Tr.¹⁰ 412, Langer Decl., Ex. 3) (emphasis added). *See Pharmadyne*, 32 F.

Supp. 2d at 301.

- Based on the foregoing undisputed evidence, the *Pharmadyne* court concluded that the Tagamet® PDR entry was not material and, at most, was cumulative of the prior art that was considered by the Examiner. *See Pharmadyne*, 32 F. Supp. 2d at 310-11.

In its answering brief, defendant does nothing more than provide attorney argument and conclusory allegations contrary to the conclusions reached by the *Pharmadyne* court. The *Pharmadyne* court specifically rejected defendant's proposition that the Tagamet® PDR entry was material because the "Examiner had no reference containing a stable commercial H₂ blocker in an oral solution with ethanol." (Answ. Br. at 18). The *Pharmadyne* court found that "it is difficult to see the connection between the Tagamet reference and the claims of the '249 patent. Pharmadyne has produced little evidence establishing a nexus between the two other than the fact that they are H₂-antagonist drugs. Accordingly, materiality has not been demonstrated." *Pharmadyne*, 32 F. Supp. 2d at 310 (citing *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1421 (Fed. Cir. 1989)). Defendant's conclusory arguments, in the absence of any supporting testimony or declaration evidence, are insufficient to raise a genuine issue of material fact and defeat Glaxo's motion for summary judgment. *See Biotec*, 249 F.3d at 1353 ("It is well

¹⁰ "Long Tr." refers to the trial testimony of Dr. David Long in the *Pharmadyne* case.

established that conclusory statements of counsel or a witness . . . do not raise a genuine issue of fact.”).

Defendant also fails to cite any evidence that Dr. Long made a conscious decision to withhold the Tagamet® PDR entry from the PTO. (Answ. Br. at 20).¹¹ One who alleges inequitable conduct arising from a failure to disclose must offer clear and convincing evidence of “knowledge chargeable to the applicant of that prior art and of its materiality” and of “a *deliberate decision* to withhold a known material reference.” *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178, 1181 (Fed. Cir. 1995) (emphasis added). Defendant’s failure to cite any supporting evidence to support its assertion of alleged deceptive intent by Dr. Long is fatal to its inequitable conduct defense concerning the Tagamet® PDR entry. Glaxo submits that there are no triable issues of material fact to support defendant’s allegations of materiality and intent concerning the Tagamet® PDR entry, and Glaxo respectfully requests dismissal of this defense.

2. There Are No Triable Issues Of Material Fact To Support Defendant’s Allegations Of Materiality And Intent Concerning Dr. Hempenstall’s Decision To Exclude Certain Unreliable Stability Data From His Declaration Submitted To The PTO

Defendant’s assertion that Dr. Hempenstall “cherry-picked” or “hid” information or data from the PTO is nothing more than conclusory, unsupported attorney argument. (Answ. Br. at 9, 15). Defendant fails to acknowledge any of Dr. Hempenstall’s testimony regarding his bona fide reasons for excluding both favorable and unfavorable stability data that he considered unreliable from his Declaration. *See Pharmadyne*, 32 F. Supp. 2d at 313. (*See also Hempenstall Tr.*)¹²

¹¹ Defendant’s speculation of an alleged “corporate culture of non-disclosure” is not supported by citation to any evidence and is utterly without basis. (Answ. Br. at 20).

¹² “Hempenstall Tr.” refers to the trial testimony of Dr. John Hempenstall in the *Pharmadyne* case.

4245-61, 4280, 4294, 4334-39, Langer Decl., Ex. 16; Hempenstall Tr. 4317-19, 4330, Langer 2d Suppl. Decl., Ex. 2).

a.

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Dr. Hempenstall's Declaration contains a significant amount of stability study data to support the finding of a stabilizing effect of ethanol on ranitidine in an aqueous formulation for oral administration. ('249 File History at G000208-211, Langer Decl., Ex. 10).

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Dr. Hempenstall testified in the *Pharmadyne* case that his decision to exclude certain stability data was based on his determination that the data was unreliable. *See Pharmadyne*, 32 F. Supp. 2d at 312. (*See also* Hempenstall Tr. 4250-56, Langer Decl., Ex. 16). The United Kingdom data contained an outlier sample, SP88/026, a formulation with ethanol stored at 45°C. *See id.* (*See also* Hempenstall Tr. 4250-51, Langer Decl., Ex. 16). Dr. Hempenstall concluded that the sample was an outlier because the rate constant figure for SP88/026 was substantially off-scale in comparison to the other samples with ethanol at that temperature. *See id.* (*See also* Hempenstall Tr. 4250-51, Langer Decl., Ex. 16). The fact that it was an outlier was confirmed by the fact that the statistician, who conducted and evaluated statistical analyses of the stability studies used by Dr. Hempenstall to prepare his Declaration, was unable to pool or combine the 45°C data. *See id.* (*See also* Hempenstall Tr. 4250-51, Langer Decl., Ex. 16; G026934, Table 1.2, Langer Decl., Ex. 17; Hempenstall Tr. 4317-19, Langer 2d Suppl. Decl., Ex. 2).

Dr. Hempenstall's decision not to include the 20°C data for both ethanol and non-ethanol formulations from the United States stability studies stemmed from his conclusion that the

amount of the degradation of the drug product over the three year period of the study was so insignificant that it precluded him from drawing any reliable conclusions about the formulations. *See Pharmadyne*, 32 F. Supp. 2d at 312. (*See also* Hempenstall Tr. 4252-56, Langer Decl., Ex. 16). Dr. Hempenstall explained that in order to make comparisons of the formulations it was necessary that the samples showed a greater amount of degradation of the drug product. *See id.* (*See also* Hempenstall Tr. 4252-56, Langer Decl., Ex. 16). At the higher temperatures, degradation of the drug product was occurring at a greater rate, on the order of four times greater. *See id.* (*See also* Hempenstall Tr. 4252-56, Langer Decl., Ex. 16). Dr. Hempenstall was firm in his testimony that the validity of data comparing the stability of formulations is greater where there is a greater amount of degradation occurring. *See id.* (*See also* Hempenstall Tr. 4250-56, Langer Decl., Ex. 16). Defendant has offered no evidence to the contrary.

The following line of questioning on cross-examination by opposing counsel and then by Judge Davis is illustrative of the bona fide reasons provided by Dr. Hempenstall for excluding certain unreliable stability data:

Q Why did you not include the UK data, just generally?

* * *

A Having reviewed it, I believed it was unreliable and unrepresentative. Rather than cherry pick the data at 30 degrees and submit it in my declaration, I decided to put it all to one side.

* * *

THE COURT: Part of what is being urged on the Court in this case is an argument that basically says this: The UK ingredients were essentially the same as the U.S. ingredients. On what rational basis would one acting in good faith exclude test results that were equivocal or unfavorable on the same ingredients?

THE WITNESS: I think if the data makes you believe there is something odd about the results, then that is reason to do

so, to set them aside, and that's the judgment that I made.

THE COURT: A possible response to that is under that approach if you have a set of data 50 percent of which is what you might call bad because it's not consistent with the hypothesis, and 50 percent of it is consistent with the hypothesis, under your approach, arguably, you exclude the bad 50 percent and submit the other 50 percent and represent it as the data. Do you see how that argument can be formulated?

THE WITNESS: I can see your point. As I said, I looked at the data as a whole, I saw inconsistencies and problems in terms of the SP88/026 and I could have included the data at 20 degrees, but if I had taken that out and used it like that I would be accused of taking out of context. It's easier to say there is something wrong here, let's put it to one side and look at the rest of the data. We have three other programs and they all clearly show an enhancing effect.

* * *

THE WITNESS: If you look at all the data it's overwhelming that there is an effect of ethanol. I explained how I went through all the process. There are four studies here. The UK, there is some good data in the UK, the U.S., the Zantac Syrup with different concentrations and the ranitidine solution. Three are very supportive. The UK, it's difficult.

THE COURT: Okay.

THE WITNESS: I believe what I did was appropriate. If I was asked to do this again I would do it the same way.

(Hempenstall Tr. 4330, Langer 2d Suppl. Decl., Ex. 2; Hempenstall Tr. 4334-35, 4339, Langer Decl., Ex 16). As demonstrated by this and the other undisputed evidence, Dr. Hempenstall acted in good faith and unequivocally believed that the data was unreliable. A court must consider the evidence of good faith before drawing an inference that culpable conduct has been clearly and convincingly demonstrated. *See Purdue Pharma*, 438 F.3d at 1134 (concluding that the trial court erred in discounting evidence of good faith as part of inequitable conduct analysis). "Alleged conduct must not amount merely to the improper performance of, or omission of, an act

one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the *specific intent* to accomplish an act that the applicant ought not to have performed, *viz.*, misleading or deceiving the USPTO.” *Molins*, 48 F.3d at 1181 (emphasis added). Dr. Hempenstall used his experience and sound professional judgment in deciding to exclude the unreliable stability data from his Declaration. *See Pharmadyne*, 32 F. Supp. 2d at 312-313. (*See also* Hempenstall Tr. 4249-61, 4280, 4294, 4334-4339, Langer Decl., Ex. 16; Hempenstall Tr. 4317-19, 4330, Langer 2d Suppl. Decl., Ex. 2; ‘249 File History at G000208-211, Langer Decl., Ex. 10; Anderson Rebuttal Rpt. ¶¶ 37-39). Defendant has not pointed to any specific evidence to prove otherwise or offered any new evidence to support a finding of intent to mislead the PTO.¹³

¹³ Defendant’s assertion that Glaxo has used incomplete data in this case to demonstrate that defendant’s formulation infringes the claims of the ‘249 patent is wrong and is irrelevant to Glaxo’s summary judgment motion to dismiss defendant’s inequitable conduct defense. (Answ. Br. at 16 n.13).

REDACTED

As to the data referred to by defendant in defendant’s deposition Exhibit 9, that data was submitted to the FDA in November 1994, long after the Hempenstall Declaration was submitted to the PTO in May 1991 and long after issuance of the ‘249 patent in November 1991. (G023189-90, Langer 2d Suppl. Decl., Ex. 4; ‘249 File History at G000205-11, Langer Decl., Ex. 10; ‘249 Patent, Langer Decl., Ex. 1).

REDACTED

b. The Bird Memo Was Considered By The *Pharmadyne* Court – This Memo Was Immaterial And There Is No Basis To Infer An Intent To Deceive From It

Defendant's reliance on a memorandum prepared by Mrs. Fiona Bird (the "Bird memo"),¹⁴ a Glaxo scientist, as support for its inequitable conduct claim is nothing more than a red herring. The Bird memo contains stability study information that was not subject to the type of statistical analysis that Dr. Hempenstall required before he submitted his Declaration to the PTO. *See Pharmadyne*, 32 F. Supp. 2d at 311. (*See also* Hempenstall Tr. 4245-49, Langer Decl., Ex. 16). The *Pharmadyne* court specifically considered the Bird memo and did not infer from it any intent by Dr. Hempenstall to mislead the PTO. *Id.*

REDACTED

REDACTED

¹⁵ As noted in footnote 13, "Anderson Suppl. Rpt." refers to "Bradley D. Anderson, Ph.D. Fed. R. Civ. P. 26(a)(2) Supplemental Expert Witness Report Responsive to Prof. Kibbe's Deposition Testimony" attached as Exhibit C to the Anderson Declaration.

REDACTED

¹⁶ “Anderson Dep.” refers to the deposition testimony of Glaxo expert witness, Bradley D. Anderson, Ph.D., taken in this matter on June 8, 2006.

in the *Pharmadyne* case, which was credited by Judge Davis. See *Pharmadyne*, 32 F. Supp. 2d at 311-13. (See also Hempenstall Tr. 4245-49, Langer Decl., Ex. 16).

REDACTED

In his Declaration provided to the PTO, Dr. Hempenstall provides the results of a proper statistical analysis of the stability data for the same formulations that were referred to in the Bird memo with varying percentages of ethanol (*i.e.*, 0%, 2.5%, 5%, 7.5% and 10% ethanol).

REDACTED The table in Paragraph 6 of the Hempenstall Declaration provides lower 95% confidence limits for the time (in months) for 5% ranitidine loss in syrup formulations at 37°C and 45°C as a function of % ethanol. ('249 File History at G000211 ¶ 6, Langer Decl., Ex. 10; **REDACTED** He notes that this table demonstrates the "clear advantageous effects of the presence of ethanol" on the stability of ranitidine. (*Id.*). Dr. Hempenstall's statements in his Declaration more correctly reflect the stability data available to Glaxo at the time of his Declaration than the statements by Mrs. Bird in the Bird memo, because Dr. Hempenstall's statements were based on a statistical analysis. **REDACTED**

REDACTED

The Bird memo was, therefore, immaterial to the prosecution of the applications that led to the '249 patent and does not support any inference of an intent to mislead the PTO.

In sum, there are no triable issues of material fact to support defendant's allegations of materiality and intent concerning Dr. Hempenstall's decision to exclude certain unreliable stability data from his Declaration submitted to the PTO. Glaxo respectfully requests dismissal of this defense.

B. The Conclusions Of The *Pharmadyne* Court, And Its Highly Persuasive Analysis And Finding Of No Inequitable Conduct, Have Not Been Altered By Any New Evidence Or Arguments

Glaxo explains in its opening brief the facts of *Glaxo v. Pharmadyne* and that court's rejection of Pharmadyne's allegations of inequitable conduct. The *Pharmadyne* court's finding of no inequitable conduct may collaterally estop defendant under the circumstances of this case.¹⁷ Even if defendant is not so estopped, the *Pharmadyne* court's analysis and conclusions are highly persuasive and have not been altered by any new arguments or evidence raised by defendant in this case. Defendant has mischaracterized the *Pharmadyne* court's analyses and

¹⁷ The prerequisites for the application of collateral estoppel or issue preclusion are satisfied when: "(1) the issue sought to be precluded [is] the same as that involved in the prior action; (2) that issue [was] actually litigated; (3) it [was] determined by a final and valid judgment; and (4) the determination [was] essential to the prior judgment." *Burlington*, 63 F.3d at 1231-32 (quoting *In re Graham*, 973 F.2d 1089, 1097 (3d Cir. 1992)). "Complete identity of the parties in the two suits is not required for the application of issue preclusion." *Id.* at 1232. These prerequisites are all met in this case, as demonstrated herein and by Glaxo's opening brief. Defendant affirmatively chose not to take any fact discovery and to rely on the same arguments and evidence presented by Pharmadyne, a generic company that had the same motive that defendant has in this case – to argue that the '249 patent is unenforceable due to inequitable conduct, which would allow defendant to sell its generic drug product in the United States prior to the expiration of the '249 patent. By failing to depose Dr. Long and Dr. Hempenstall and by affirmatively choosing to rely on the same arguments and evidence as in the *Pharmadyne* case, defendant has stepped into the shoes of Pharmadyne. Defendant, therefore, had "a fair opportunity procedurally, substantively and evidentially to pursue [its] claim the first time." *Blonder-Tongue*, 402 U.S. at 333 (quoting *Eisel v. Columbia Packing Co.*, 181 F. Supp. 298, 301 (D. Mass. 1960)).

conclusions. The *Pharmadyne* court rejected the identical arguments based on the identical evidence raised by defendant here. See *Pharmadyne*, 32 F. Supp. 2d at 310-13. Defendant cannot satisfy its burden of proof or set forth specific material facts demonstrating a genuine issue for trial by simply saying the *Pharmadyne* court was wrong.

IV. CONCLUSION

For the reasons set forth above and in Glaxo's opening brief, Glaxo respectfully submits that there is no genuine issue of material fact, and it is entitled to entry of summary judgment in its favor, dismissing Teva USA's Third Affirmative Defense and corresponding counterclaim (Count III) and Teva Israel's Third and Fourth Affirmative Defenses alleging inequitable conduct.

Dated: August 25, 2006

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CERTIFICATE OF SERVICE

I hereby certify that on August 25, 2006, I filed **PLAINTIFF GLAXO'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT DISMISSING DEFENDANTS' AFFIRMATIVE DEFENSES AND CORRESPONDING COUNTERCLAIM ALLEGING INEQUITABLE CONDUCT DURING THE PROSECUTION OF PATENT NO. 5,068,249** with the Clerk of Court and will hand deliver such filing to the following:

Josy W. Ingersoll, Esq.
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I hereby certify that on August 25, 2006, I have served via Federal Express, the document to the following non-registered participants:

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REDACTED
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